FEB 16 2006

510(K) SUMMARY

Submitter's Name:	Michael C. Garcia
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Contact:	David E. Curtin (847) 473-6079
Date Prepared:	12/09/05
Trade Name:	HomeChoice Automated Personal Cycler
Common Name:	APD Cycler
Classification Name:	Peritoneal dialysis system and accessories per 21 CFR 876.5630
Equivalent Predicate:	HomeChoice Automated Personal Cycler Peritoneal Dialysis System (K923065 and K012988)
Device Description:	The HomeChoice Automated Personal Cycler, version 8.9 software is used for automatic control of dialysate solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis therapy. The HomeChoice Automated Personal Cycler automatically cycles peritoneal dialysis fluid in the amounts and time prescribed by a clinician.

Intended Use:	The HomeChoice Automated Personal Cycler is intended for automatic control of dialysate solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis.
Summary of the Technological Characteristics Compared to the Predicate Device:	The general design and material of the HomeChoice Automated Personal Cycler is identical to the HomeChoice Automated Personal Cycler cleared under K923065 & K012988. It does not raise any new types of safety and effectiveness issues when compared to the predicate product
Clinical Data:	N/A
Conclusions Drawn	Validation and Verification testing was successful in demonstrating that all design requirements have been met. Bench testing was performed on the HomeChoice Automated Personal Cycler to support substantial equivalence to the predicate device, as well as demonstrating that the device operates as intended and is safe and efficacious. Functional testing for delivery integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.
Additional Information Requested by FDA:	None to date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2006

David E. Curtin, RAC
Associate Director, Global Regulatory Affairs
Baxter Healthcare Corporation
Renal Division, MPGR-A2E
1620 Waukegan Road
MCGAW PARK IL 60085

Re: K053512
Trade/Device Name: HomeChoice Automated Personal Cycler, Models 5C4471 and 5C8310
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: December 15, 2005
Received: December 16, 2005

Dear Mr. Curtin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K053512

Device Name: **HomeChoice Automated Personal Cycler**

Indications For Use: HomeChoice Automated Personal Cycler

The HomeChoice Automated Personal Cycler Peritoneal Dialysis System is intended for automatic control of dialysate solution exchanges in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053512